

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

PCT

To:
EDMUND P. PFLEGER
GROSSMAN, TUCKER, PERREAULT &
PFLEGER, PLLC
55 SO. COMMERCIAL ST.
MANCHESTER, NH 03101

NOTIFICATION OF TRANSMITTAL OF
THE INTERNATIONAL SEARCH REPORT AND
THE WRITTEN OPINION OF THE INTERNATIONAL
SEARCHING AUTHORITY, OR THE DECLARATION

(PCT Rule 44.1)

R E C E I V E D
OCT 14 2008

Date of mailing
(day/month/year)

Applicant's or agent's file reference
ART017PCT GROSSMAN, TUCKER,
PERREAULT & PFLEGER, PLLC

FOR FURTHER ACTION See paragraphs 1 and 4 below

International application No.
PCT/US 07/82262

International filing date
(day/month/year) 23 October 2007 (23.10.2007)

Applicant ARTHROSURFACE INCORPORATED

1. ☒ The applicant is hereby notified that the international search report and the written opinion of the International Searching Authority have been established and are transmitted herewith.

Filing of amendments and statement under Article 19:

The applicant is entitled, if he so wishes, to amend the claims of the international application (see Rule 46):

When? The time limit for filing such amendments is normally two months from the date of transmittal of the international search report.

Where? Directly to the International Bureau of WIPO, 34 chemin des Colombettes
1211 Geneva 20, Switzerland, Facsimile No.: +41 22 740 1435

For more detailed instructions, see the notes on the accompanying sheet.

2. ☐ The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect and the written opinion of the International Searching Authority are transmitted herewith.

3. ☐ **With regard to the protest** against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:

☐ the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.

☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. Reminders

Shortly after the expiration of **18 months** from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau as provided in Rules 90bis.1 and 90bis.3, respectively, before the completion of the technical preparations for international publication.

The applicant may submit comments on an informal basis on the written opinion of the International Searching Authority to the International Bureau. The International Bureau will send a copy of such comments to all designated Offices unless an international preliminary examination report has been or is to be established. These comments would also be made available to the public but not before the expiration of 30 months from the priority date.

Within **19 months** from the priority date, but only in respect of some designated Offices, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase **until 30 months** from the priority date (in some Offices even later); otherwise, the applicant must, **within 20 months** from the priority date, perform the prescribed acts for entry into the national phase before those designated Offices.

In respect of other designated Offices, the time limit of **30 months** (or later) will apply even if no demand is filed within 19 months.

See the Annex to Form PCT/IB/301 and, for details about the applicable time limits, Office by Office, see the *PCT Applicant's Guide*, Volume II, National Chapters and the WIPO Internet site.

Name and mailing address of the ISA/US
Mail Stop PCT, Attn: ISA/US
Commissioner for Patents
P.O. Box 1450, Alexandria, Virginia 22313-1450
Facsimile No. 571-273-3201

Authorized officer:

Lee W. Young

PCT Helpdesk: 571-272-4300
PCT OSP: 571-272-7774

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

PCT

To:
EDMUND P. PFLEGER
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09 OCT 2008

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ART017PCT

FOR FURTHER ACTION See paragraphs 1 and 4 below

International application No.
PCT/US 07/82262

International filing date
(day/month/year) 23 October 2007 (23.10.2007)

Applicant **ARTHROSURFACE INCORPORATED**

1. ☒ The applicant is hereby notified that the international search report and the written opinion of the International Searching Authority have been established and are transmitted herewith.

Filing of amendments and statement under Article 19:

The applicant is entitled, if he so wishes, to amend the claims of the international application (see Rule 46):

When? The time limit for filing such amendments is normally two months from the date of transmittal of the international search report.

Where? Directly to the International Bureau of WIPO, 34 chemin des Colombettes
1211 Geneva 20, Switzerland, Facsimile No.: +41 22 740 1435

For more detailed instructions, see the notes on the accompanying sheet.

2. ☐ The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect and the written opinion of the International Searching Authority are transmitted herewith.

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☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. **Reminders**

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The applicant may submit comments on an informal basis on the written opinion of the International Searching Authority to the International Bureau. The International Bureau will send a copy of such comments to all designated Offices unless an international preliminary examination report has been or is to be established. These comments would also be made available to the public but not before the expiration of 30 months from the priority date.

Within **19 months** from the priority date, but only in respect of some designated Offices, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase **until 30 months** from the priority date (in some Offices even later); otherwise, the applicant must, **within 20 months** from the priority date, perform the prescribed acts for entry into the national phase before those designated Offices.

In respect of other designated Offices, the time limit of **30 months** (or later) will apply even if no demand is filed within 19 months.

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P.O. Box 1450, Alexandria, Virginia 22313-1450
Facsimile No. 571-273-3201

Authorized officer:

Lee W. Young

PCT Helpdesk: 571-272-4300
PCT OSP: 571-272-7774

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference ART017PCT	FOR FURTHER ACTION <div style="float: right; font-size: small;">see Form PCT/ISA/220 as well as, where applicable, item 5 below.</div>	
International application No. PCT/US 07/82262	International filing date (<i>day/month/year</i>) 23 October 2007 (23.10.2007)	(Earliest) Priority Date (<i>day/month/year</i>) 23 October 2006 (23.10.2006)
Applicant ARTHROSURFACE INCORPORATED		

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 2 sheets.

☐ It is also accompanied by a copy of each prior art document cited in this report.

1. Basis of the report

a. With regard to the **language**, the international search was carried out on the basis of:

- ☒ the international application in the language in which it was filed.
☐ a translation of the international application into _____ which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

b. ☐ This international search report has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43.6*bis*(a)).

c. ☐ With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, see Box No. I.

2. ☐ **Certain claims were found unsearchable** (see Box No. II).

3. ☐ **Unity of invention is lacking** (see Box No. III).

4. With regard to the **title**,

- ☒ the text is approved as submitted by the applicant.
☐ the text has been established by this Authority to read as follows:

5. With regard to the **abstract**,

- ☒ the text is approved as submitted by the applicant.
☐ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. With regard to the **drawings**,

- a. the figure of the **drawings** to be published with the abstract is Figure No. 7
☒ as suggested by the applicant.
☐ as selected by this Authority, because the applicant failed to suggest a figure.
☐ as selected by this Authority, because this figure better characterizes the invention.
- b. ☐ none of the figures is to be published with the abstract.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 07/82262

A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - A61B 17/00 (2008.04)

USPC - 606/80

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC(8) - A61B 17/00 (2008.04)

606/80

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
606/53, 79, 81, 167, 170, 176, 177, 178, 179, 180

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

PubWEST(USPT,PGPB,EPAB,JPAB); Google Scholar;

Search Terms Used: retrograde excision, cut, mill, bone, removable, pivot pin, ball joint, ball couple

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2006/0195112 A1 (EK) 31 August 2006 (31.08.2006) Entire document, especially para [0057]-[0059], [0064] - [0068], [0115], [0116] and FIGS. 5-9, 11.	1, 6-9 and 11-20
Y		2-5 and 10
Y	US 2003/0171756 A1 (FALLIN et al.) 11 September 2003 (11.09.2003) para [0016], [0060], [0063], [0069], [0080] and FIG. 3.	2-5 and 10

☐ Further documents are listed in the continuation of Box C.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search

05 October 2008 (05.10.2008)

Date of mailing of the international search report

09 OCT 2008

Name and mailing address of the ISA/US

Mail Stop PCT, Attn: ISA/US, Commissioner for Patents
P.O. Box 1450, Alexandria, Virginia 22313-1450
Facsimile No. 571-273-3201

Authorized officer:

Lee W. Young

PCT Helpdesk: 571-272-4300
PCT OSP: 571-272-7774

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

To: EDMUND P. PFLEGER
GROSSMAN, TUCKER, PERREAULT &
PFLEGER, PLLC
55 SO. COMMERCIAL ST.
MANCHESTER, NH 03101

Date of mailing
(day/month/year)

09 OCT 2008

Applicant's or agent's file reference
ART017PCT

FOR FURTHER ACTION

See paragraph 2 below

International application No.

PCT/US 07/82262

International filing date (day/month/year)

23 October 2007 (23.10.2007)

Priority date (day/month/year)

23 October 2006 (23.10.2006)

International Patent Classification (IPC) or both national classification and IPC

IPC(8) - A61B 17/00 (2008.04)

USPC - 606/80

Applicant ARTHROSURFACE INCORPORATED

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/US
Mail Stop PCT, Attn: ISA/US
Commissioner for Patents
P.O. Box 1450, Alexandria, Virginia 22313-1450
Facsimile No. 571-273-3201

Date of completion of this opinion

05 October 2008 (05.10.2008)

Authorized officer:

Lee W. Young

PCT Helpdesk: 571-272-4300
PCT OSP: 571-272-7774

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/US 07/82262

Box No. I Basis of this opinion

1. With regard to the **language**, this opinion has been established on the basis of:
☒ the international application in the language in which it was filed.
☐ a translation of the international application into _____ which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).
2. ☐ This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43*bis*.1(a))
3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, this opinion has been established on the basis of:
 - a. type of material
☐ a sequence listing
☐ table(s) related to the sequence listing
 - b. format of material
☐ on paper
☐ in electronic form
 - c. time of filing/furnishing
☐ contained in the international application as filed
☐ filed together with the international application in electronic form
☐ furnished subsequently to this Authority for the purposes of search
4. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
5. Additional comments:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.

PCT/US 07/82262

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	2-5, 10, 19, 20	YES
	Claims	1, 6-9 and 11-18	NO
Inventive step (IS)	Claims	None	YES
	Claims	1-20	NO
Industrial applicability (IA)	Claims	1-20	YES
	Claims	None	NO

2. Citations and explanations:

Claims 1, 6-9 and 11-18 lack novelty under PCT Article 33(2) as being anticipated by US 2006/0195112 A1 to (Ek).

As per claim 1, Ek describes an excision tool (para [0064]) comprising:

a shaft (shaft 72, FIG. 7, para [0064]); and

a cutter (cutter 74, FIG. 7, para [0064]) configured to be coupled to said shaft to provide said cutter rotatable with said shaft (para [0066]) and tiltable relative to said shaft (FIG. 8, 9).

As per claim 6, Ek describes a system for excising a portion of an articular surface (para [0064]), said system comprising:

a stop sleeve comprising an axial bore (sheath 54, FIG. 8, para [0057]);

a central shaft rotatably and slidably receivable in said bore (shaft 72, FIGS. 6-7, para [0065]);

a cutter (cutter 74, FIG. 7, para [0064]) configured to be coupled to said central shaft to permit said cutter to rotate with said central shaft (para [0066]) and to be tiltable relative to said central shaft (FIG. 8, 9).

As per claim 7, Ek describes a system according to claim 6, wherein said stop sleeve is configured to be at least partially disposed in an access tunnel defined in a bone (FIG. 8, para [0057], [0064]), said stop sleeve being axially translatable within said access tunnel (para [0057], [0058]).

As per claim 8, Ek describes a system according to claim 7, wherein said stop sleeve comprises an external thread configured to threadably engage bone defining an access tunnel (FIG. 6, para [0057], [0058]).

As per claim 9, Ek describes a system according to claim 7, wherein said central shaft is configured to be axially translatable with said stop sleeve (para [0065]).

As per claim 11, Ek describes a system according to claim 6, wherein said cutter comprises a bearing surface (shaft 75, FIG. 11) configured to travel along a distal end of said stop sheath (para [0068]).

As per claim 12, Ek describes a method of excising a portion of an articular surface (para [0115]) comprising:

providing an access tunnel extending through a bone to said articular surface (para [0057], [0058], [0115], FIG. 5);

inserting a central shaft at least partially into said access tunnel (para [0057], [0058], [0115], [0116], FIG. 8);

coupling a cutter to said central shaft (cutter 74, FIG. 7, para [0064]), said cutter tiltable relative to said central shaft (FIG. 8, 9);

rotating said cutter (para [0066]); and

applying a retrograde force to said cutter to urge said cutter into said articular surface (para [0067]).

As per claim 13, Ek describes a method according to claim 12, wherein rotating said cutter comprises applying a rotational force to said cutter through said central shaft (para [0067]).

As per claim 14, Ek describes a method according to claim 12, wherein applying a retrograde force comprises withdrawing said central shaft away from said articular surface (para [0067]).

As per claim 15, Ek describes a method according to claim 12, further comprising installing a stop sleeve at least partially into said access tunnel (para [0057]), said stop sleeve receiving at least a portion of said central shaft through said stop sleeve (para [0064]).

As per claim 16, Ek describes a method according to claim 15, wherein applying a retrograde force comprises withdrawing said stop sleeve and said central shaft away from said articular surface (para [0067], [0068]).

As per claim 17, Ek describes a method according to claim 16, wherein said stop sheath is threadably engaged in said access tunnel, and withdrawing said stop sleeve and said shaft comprises threadably translating said stop sleeve away from said articular surface (para [0058] - para [0059]; [0067] - [0068]; FIGS. 8-9).

As per claim 18, Ek describes a method according to claim 16, comprising positioning a bearing surface of said cutter adjacent to a distal end of said stop sleeve and withdrawing said cutter and said stop sleeve away from said articular surface (para [0068]).

-----Please See Continuation Sheet -----

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/US 07/82262

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of:
Box V.2. Citations and explanations:

Claims 19 and 20 lack an inventive step under PCT Article 33(3) as being obvious over Ek.

As per claim 19, Ek describes a method according to claim 15, comprising providing a guide sleeve (para [0115]), but does not show the guide sleeve positioned at least partially through said stop sleeve, said central shaft extending at least partially through said guide sleeve. However, such a configuration would have been obvious to one of ordinary skill in the art as it would allow the stop sleeve to be properly positioned, and eliminate the need to remove the guide sleeve before excision by the central shaft occurred, reducing the complexity of the procedure.

As per claim 20, Ek describes a method according to claim 19, but does not show further positioning a distal end of said guide sleeve adjacent to said cutter, said guide sleeve directing an orientation of said cutter during rotation thereof. Such a configuration would have been obvious to one of ordinary skill in the art as it would allow predetermined definition of an excision orientation, eliminating the need for adjusting the cutter during the procedure and preventing possible errors in cutting.

Claims 2-5 and 10 lack an inventive step under PCT Article 33(3) as being obvious over Ek in view of US 2003/0171756 A1 to Fallin et al. (hereinafter: Fallin).

As per claim 2, Ek describes an apparatus according to claim 1, but fails to describe wherein said cutter is configured to be removably coupled to said shaft. However, Fallin describes a bone excision tool (para [0016]) which includes a cutter element (mill 300, FIG. 3) that is removable from the shaft (para [0063], [0069]). It would have been obvious to one skilled in the art to provide a removable cutter as described by Fallin on the device of Ek so as to be able to replace the cutter for alternate cutters of different sizes, or for replacing worn cutters.

As per claim 3, Ek describes an apparatus according to claim 1, wherein said cutter comprises a coupling (para [0071]), said cutter configured to be tiltable relative to said central shaft about said coupling (FIG. 8, 9), but fails to describe the coupling being a ball. However, Fallin describes a bone excision tool (para [0016]) which includes a ball coupling (para [0080]). It would have been obvious to one skilled in the art to provide a ball coupling as described by Fallin on the device of Ek so as to provide extra degrees of freedom for movement, so as to provide more complex cutting.

As per claim 4, Ek and Fallin describe an apparatus according to claim 3. Ek also teaches an apparatus wherein said shaft comprises an opening adjacent to an end of said shaft (FIG. 11), said opening sized to receive at least a portion of said cutter and said coupling (para [0068]) and Fallin describes a ball coupling (para [0080]).

As per claim 5, Ek describes an apparatus according to claim 1, but fails to describe wherein said cutter is configured to be coupled to said shaft via a pivot pin. However, Fallin describes a bone excision tool (para [0016]) which includes an element attached to the sleeve with a pivot pin (para [0060] - para [0061]). It would have been obvious to one skilled in the art to provide a pivot pin coupling as described by Fallin on the device of Ek so as to provide a simple, easily adjustable coupling between the cutter and shaft.

As per claim 10, Ek describes a system according to claim 6, wherein said cutter comprises a coupling (para [0071]), said cutter configured to be tiltable relative to said central shaft about said coupling (FIG. 9), but fails to describe the coupling being a ball. However, Fallin describes a bone excision tool (para [0016]) which includes a ball coupling (para [0080]). It would have been obvious to one skilled in the art to provide a ball coupling as described by Fallin on the device of Ek so as to provide extra degrees of freedom for movement, so as to provide more complex cutting.

Claims 1-20 have industrial applicability as defined by PCT Article 33(4) because the subject matter can be made or used in industry.

NOTES TO FORM PCT/ISA/220

These Notes are intended to give the basic instructions concerning the filing of amendments under Article 19. The Notes are based on the requirements of the Patent Cooperation Treaty, the Regulations and the Administrative Instructions under that Treaty. In case of discrepancy between these Notes and those requirements, the latter are applicable. For more detailed information, see also the *PCT Applicant's Guide*, a publication of WIPO.

In these Notes, "Article," "Rule" and "Section" refer to the provisions of the PCT, the PCT Regulations and the PCT Administrative Instructions, respectively.

INSTRUCTIONS CONCERNING AMENDMENTS UNDER ARTICLE 19

The applicant has, after having received the international search report and the written opinion of the International Searching Authority, one opportunity to amend the claims of the international application. It should however be emphasized that, since all parts of the international application (claims, description and drawings) may be amended during the international preliminary examination procedure, there is usually no need to file amendments of the claims under Article 19 except where, e.g. the applicant wants the latter to be published for the purposes of provisional protection or has another reason for amending the claims before international publication. Furthermore, it should be emphasized that provisional protection is available in some States only (see *PCT Applicant's Guide*, Volume I/A, Annexes B1 and B2).

The attention of the applicant is drawn to the fact that amendments to the claims under Article 19 are not allowed where the International Searching Authority has declared, under Article 17(2), that no international search report would be established (see *PCT Applicant's Guide*, Volume I/A, paragraph 296).

What parts of the international application may be amended ?

Under Article 19, only the claims may be amended.

During the international phase, the claims may also be amended (or further amended) under Article 34 before the International Preliminary Examining Authority. The description and drawings may only be amended under Article 34 before the International Preliminary Examining Authority.

Upon entry into the national phase, all parts of the international application may be amended under Article 28 or, where applicable, Article 41.

When ? Within 2 months from the date of transmittal of the international search report or 16 months from the priority date, whichever time limit expires later. It should be noted, however, that the amendments will be considered as having been received on time if they are received by the International Bureau after the expiration of the applicable time limit but before the completion of the technical preparations for international publication (Rule 46.1).

Where not to file the amendments ?

The amendments may only be filed with the International Bureau and not with the receiving Office or the International Searching Authority (Rule 46.2).

Where a demand for international preliminary examination has been/is filed, see below.

How ? Either by cancelling one or more entire claims, by adding one or more new claims or by amending the text of one or more of the claims as filed.

A replacement sheet must be submitted for each sheet of the claims which, on account of an amendment or amendments, differs from the sheet originally filed.

All the claims appearing on a replacement sheet must be numbered in Arabic numerals. Where a claim is cancelled, no renumbering of the other claims is required. In all cases where claims are renumbered, they must be renumbered consecutively (Section 205(b)).

The amendments must be made in the language in which the international application is to be published.

What documents must/may accompany the amendments ?

Letter (Section 205(b)):

The amendments must be submitted with a letter.

The letter will not be published with the international application and the amended claims. It should not be confused with the "Statement under Article 19(1)" (see below, under "Statement under Article 19(1)").

The letter must be in English or French, at the choice of the applicant. However, if the language of the international application is English, the letter must be in English; if the language of the international application is French, the letter must be in French.

NOTES TO FORM PCT/ISA/220 (continued)

The letter must indicate the differences between the claims as filed and the claims as amended. It must, in particular, indicate, in connection with each claim appearing in the international application (it being understood that identical indications concerning several claims may be grouped), whether

- (i) the claim is unchanged;
- (ii) the claim is cancelled;
- (iii) the claim is new;
- (iv) the claim replaces one or more claims as filed;
- (v) the claim is the result of the division of a claim as filed.

The following examples illustrate the manner in which amendments must be explained in the accompanying letter:

1. [Where originally there were 48 claims and after amendment of some claims there are 51]:
"Claims 1 to 29, 31, 32, 34, 35, 37 to 48 replaced by amended claims bearing the same numbers; claims 30, 33 and 36 unchanged; new claims 49 to 51 added."
2. [Where originally there were 15 claims and after amendment of all claims there are 11]:
"Claims 1 to 15 replaced by amended claims 1 to 11."
3. [Where originally there were 14 claims and the amendments consist in cancelling some claims and in adding new claims]:
"Claims 1 to 6 and 14 unchanged; claims 7 to 13 cancelled; new claims 15, 16 and 17 added." or
"Claims 7 to 13 cancelled; new claims 15, 16 and 17 added; all other claims unchanged."
4. [Where various kinds of amendments are made]:
"Claims 1-10 unchanged; claims 11 to 13, 18 and 19 cancelled; claims 14, 15 and 16 replaced by amended claim 14; claim 17 subdivided into amended claims 15, 16 and 17; new claims 20 and 21 added."

"Statement under Article 19(1)" (Rule 46.4)

The amendments may be accompanied by a statement explaining the amendments and indicating any impact that such amendments might have on the description and the drawings (which cannot be amended under Article 19(1)).

The statement will be published with the international application and the amended claims.

It must be in the language in which the international application is to be published.

It must be brief, not exceeding 500 words if in English or if translated into English.

It should not be confused with and does not replace the letter indicating the differences between the claims as filed and as amended. It must be filed on a separate sheet and must be identified as such by a heading, preferably by using the words "Statement under Article 19(1)."

It may not contain any disparaging comments on the international search report or the relevance of citations contained in that report. Reference to citations, relevant to a given claim, contained in the international search report may be made only in connection with an amendment of that claim.

Consequence if a demand for international preliminary examination has already been filed

If, at the time of filing any amendments and any accompanying statement, under Article 19, a demand for international preliminary examination has already been submitted, the applicant must preferably, at the time of filing the amendments (and any statement) with the International Bureau, also file with the International Preliminary Examining Authority a copy of such amendments (and of any statement) and, where required, a translation of such amendments for the procedure before that Authority (see Rules 55.3(a) and 62.2, first sentence). For further information, see the Notes to the demand form (PCT/IPEA/401).

If a demand for international preliminary examination is made, the written opinion of the International Searching Authority will, except in certain cases where the International Preliminary Examining Authority did not act as International Searching Authority and where it has notified the International Bureau under Rule 66.1bis(b), be considered to be a written opinion of the International Preliminary Examining Authority. If a demand is made, the applicant may submit to the International Preliminary Examining Authority a reply to the written opinion together, where appropriate, with amendments before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later (Rule 43bis.1(c)).

Consequence with regard to translation of the international application for entry into the national phase

The applicant's attention is drawn to the fact that, upon entry into the national phase, a translation of the claims as amended under Article 19 may have to be furnished to the designated/elected Offices, instead of, or in addition to, the translation of the claims as filed.

For further details on the requirements of each designated/elected Office, see the *PCT Applicant's Guide*, Volume II.